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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,432	11/23/1998	HOWARD A. FIELDS	03063-0231US	8029
23859	7590	06/04/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/171,432

**Applicant(s)**

FIELDS ET AL.

**Examiner**

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69, 70 and 73-89 is/are pending in the application.
- 4a) Of the above claim(s) 69, 74-76 and 79-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70, 77, and 78 is/are rejected.
- 7) ☒ Claim(s) 83-89 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 69, 70, 73-89 are currently pending in the present application. Claims 70, 77, 78, and 83-89 are under consideration. Claims 69, 73-76, and 79-82 are withdrawn as to non-elected inventions.

Claims 70, 71, 77, and 78 were rejected in the prior action, mailed on December 2, 2003 (the prior action). In the Responses filed on March 1, and March 26 2004, the Applicant amended claims 70, 77, and 78; and cancelled claims 1, and 71.

2. Because this action raises new grounds of rejection, not necessitated by amendments to the claims, the action is being made Non-Final.

### ***Specification***

3. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: in the paragraph beginning on line 5 of page 13 ("Conservatively modified variations), several instances of the terms silent and conservatively appear to have typographical errors with the words being spelled as "Asilent" or "Aconservatively." In view of the amendment of the specification, the objection is withdrawn.

### ***Claim Objections***

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4. **(Prior Objection- Withdrawn)** Claim 71 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the cancellation of the claim, the objection is withdrawn.

5. **(New Objection)** Claims 77, and 83-89 are objected to because of the following informalities: these claim refer to the hepatitis A virus by its acronym (HAV) without first identifying the virus by its complete name. Appropriate correction is required.

6. **(New Objection)** Claims 70 and 77 are objected to because of the following informalities: these claims include the Markush-like language “selected from the Group consisting of SEQ ID NOS: 39 *or* 42-48.” (Emphasis added). Proper Markush format requires the use of “and” instead of “or” in the indicated claim language. See e.g. MPEP 2173.05(h). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(New Rejection)** Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on HAV peptides comprising at least one of SEQ ID NOs: 39 or 42-48, or conservative variations thereof. It is noted that the Applicant responded to a prior rejection on these grounds by reciting what was stated in the specification

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on page 13. However, the description noted by the Applicant states “individual substitutions, deletions or additions which alter, add or delete a single amino acid or a small percentage of amino acids... in an encoded sequence are [conservatively] modified variations where the alterations result in the substitution of an amino acid with a chemically similar amino acid.”

However, this language does not state that conservatively modified variations are limited to such substitutions. The language does indicate that additions or deletions may also be considered a conservative modification, but provided no means by which to determine if a particular addition or deletion is conservative in nature. Because it is not clear what constitutes a conservative variation, the claim is rejected as indefinite.

It is suggested that the term “conservative variation” be replaced with the term - - conservative substitution- -. For the purposes of this action, unless otherwise stated, the language is interpreted to read on conservative substitutions.

9. **(New Rejection)** Claims 70 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on HAV peptides comprising one of SEQ ID NOs: 39 or 42-48, and “wherein a portion from at least one of SEQ ID NOS: 38-42 is excluded.” The claims read on peptides from native HAV proteins comprising one of the indicated sequences. However, it is unclear if the quoted phrase requires that a portion of one of the indicated sequences has been deleted or otherwise excised from the claimed peptides, or if a substitution in the sequence such that the peptides do not include a sequence identical to at least one of SEQ ID NOs: 38-42. Clarification is required.

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For the purposes of this action, unless otherwise stated, the claims are interpreted as reading on native HAV sequences comprising at least one of SEQ ID NOs: 39, or 42-48, and either excluding, or including only a variant of, at least one of sequences 38-42.

10. **(New Rejection)** Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on an antigenic HAV peptide of claim 77, "wherein the peptide excludes SEQ ID NOS: 38-42." It is unclear what is meant by this claim. In particular, it is unclear if the claim is intended to exclude the complete sequence formed by the overlapping sequences of SEQ ID NOs: 38-42, but would include sequences comprising portions of the indicated sequences; or if the claim reads on the HAV peptides of claim 77 which lack any portion of the indicated sequences. It is suggested that the claim be amended to indicate that the peptide excludes - - each of SEQ ID NOs: 38-42. - - Clarification is required.

11. **(Prior Rejection-Withdrawn)** Claims 70, 71, 77, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim were rejected for specifying that the claimed peptides have a sequence selected from one group of peptides, and then further specifying that the peptide may also be selected from a larger group of sequences. In view of the amendment of claims 70 and 77, and the cancellation of claim 71, the rejection is withdrawn.

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12. **(Prior Rejection-Withdrawn)** Claim 71 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the cancellation of the claim, the rejection is withdrawn.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. **(Prior Rejection-Withdrawn)** Claim 71 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In view of the cancellation of the claim, the rejection is withdrawn.

15. **(New Rejection)** Claim 70 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims read on any isolated and antigenic HAV peptide comprising at least one of SEQ ID NOs: 39, or 42-48, or a conservative variant thereof. Thus, the claims read on any peptide found in a hepatitis A virus protein, wherein the peptide comprises a sequence

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identical to one of the indicated sequences, or a sequence varying from these sequences by at least one conservative substitution.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the instant case, while the Applicant has provided the sequences of SEQ ID NOs: 39, and 42-48, the Applicant has not provided examples of conservative variants of such peptides that may be found in other HAV isolates. The Applicant has not provided any guidance as to what conservative substitutions may be found in other isolates of HAV. Nor has the Applicant provided any means for those in the art to distinguish an HAV peptide with a conservative substitution from peptides with random conservative substitutions that are not found in nature. Because the application does not provide a representative number of examples, or any



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identifying characteristics by which those in the art could recognize the claimed genus, the claims are rejected for lack of written description.

***Claim Rejections - 35 USC § 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. **(New Rejection)** Claims 70, 77, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Dina et al. (EP 0199480- of record in the IDS of October 1998), or Linemeyer et al., J Virol 54(2): 247-55. These claims read on antigenic HAV peptides comprising at least one antigenic determinants from the groups of peptides consisting of SEQ ID NOs: 39, and 42-48, and wherein either a portion of at least one of SEQ ID NOs: 38-42 is excluded, or wherein the peptide excludes SEQ ID NOS: 38-42. For the purposes of this rejection, claim 78 is interpreted as requiring the exclusion of the complete sequence formed by the overlapping peptides of SEQ ID NOs: 38-42, but which may include portions of that sequence. It is noted that the Applicant has provided no size limitation on the term “peptide.” See, page 11 of the application (defining peptides as “chains of amino acids (typically L-amino acids) whose a carbons are linked through peptide bonds formed by a condensation reaction between the carboxyl group of the a carbon of one amino acid and the amino group of the a carbon of another amino acid”). It is also noted that the term “antigenic determinant in the claims

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requires no more than that the peptide is capable of being recognized by an antibody. See, App., page 12, lines 15-16. Thus, the claims read on any chain of amino acids comprising at least one of SEQ ID NOs: 39, and 42-48, and lacking at least a portion of one of SEQ ID NOs: 38-42, or the complete sequence comprising the sequences of SEQ ID NOs: 38-42.

Dina discloses and claims the protein disclosed in Figure 1 of the reference. Claim 5. This figure discloses a HAV polyprotein including the complete sequences of each of SEQ ID NOs: 42-48. See, Figure 1b, amino residues 779-980. The polyprotein does not comprise the complete sequence of SEQ ID NO: 38 or 39, and therefore does not comprise the complete sequence comprising the sequence of SEQ ID NOs: 38-42.

The references therefore anticipate the indicated claims.

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 70, 77, and 78 are rejected under 35 U.S.C. 102(b) as anticipated by ), or Linemeyer et al. (J Virol 54(2): 247-55) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Linemeyer in view of Dina as described above. The claims have been above.

Linemeyer also teaches an HAV polyprotein. See, page 252, Figure 7, translation of nucleotides 2835-3052. This polyprotein comprises the sequences of SEQ ID NOs: 39, 42, 47,

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and the sequence of SEQ ID NO: 43 minus the c-terminal serine (a polypeptide which would likely share an antigenic determinant with SEQ ID NO: 43). Further, the polyprotein also comprises a substitution in the sequence corresponding to SEQ ID NO: 38, and thus excludes at least a portion of the sequence.

It is noted that the reference does not teach the isolation of the disclosed polyprotein. However, even if the Linemeyer teachings do not themselves anticipate the claims, the combination of the Linemeyer and Dina references would render the claims obvious. This is because, in addition to teaching the polyprotein, Dina teaches that the protein may be used for the generation of antibodies against HAV. Page 7, col. 12. It would therefore have been obvious to those in the art to substitute the polyprotein of Linemeyer for the polyprotein of Linemeyer as the two polyproteins would be recognized as functional equivalents in the art in that both are HAV proteins which may be used for the generation of anti-HAV antibodies.

### ***Conclusion***


20. The subject matter of claims 83-89 appears to be allowable over the prior art.

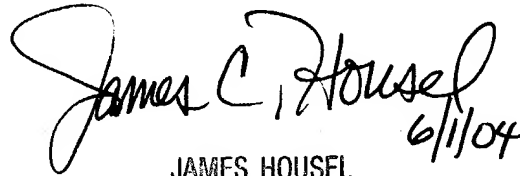
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
6/1/04